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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/190,887	11/12/98	CORMIER M	ARC2589CIP1

HM12/1208

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EXAMINER	
CELSA, B	
ART UNIT	**PAPER NUMBER**
1618	7

DATE MAILED: 12/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

file copy

Office Action Summary

Application No.	Applicant(s)
09/190,887	Cormier et al.
Examiner	**Group Art Unit**
Bennett Celsa	1618

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-20* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-20 are currently pending.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to dipeptide containing compositions, classified, for example, in class 260, subclass 998+.

II. Claims 9-11, drawn to a transdermal delivery apparatus, classified, for example, in class 128 , subclass 200+ .

III.. Claims 12-20, drawn to a method of buffering a drug or electrolyte, classified, for example, in class 514 , subclass 2+.

1. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are drawn to totally different classes of inventions (e.g. composition v. apparatus) and the apparatus vis a vis the composition has different modes of operation, different functions, or different effects and need not employ the composition of Group I.

2. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced

with another materially different product(s) such as the use of amino acid buffers or use of "classic buffers" (e.g. TRIS) as buffering agents (e.g. see specification pages 3-5)..

3. Inventions II and II are drawn to totally different classes of inventions (e.g. apparatus v. method) in which the method does not necessitate the use of the apparatus and vice versa.

4. Because these inventions are distinct for the reasons given above and

a. have acquired a separate status in the art as shown by their different classification;

b. require different and separately burdensome manual/computer name, classification and bibliographic searches; and

c. because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

Upon the election of any of the above inventions (e.g. Group I, II or III) the following election of species is required.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. "Drug" or "electrolyte"

b. "dipeptide" buffer:

A drug encompasses a number of variably structured generic compounds (e.g. proteins, nucleotides, lipids" and specific compounds (e.g. Ara C, insulin, etc) which differ in structure, physicochemical properties and/or means of manufacture and/or use and necessitate different and

separately burdensome manual and computer structure, classification, name and bibliographic searches.

Similarly, dipeptides are composed of different amino acids which lead to different structure, physicochemical properties and/or means of manufacture and/or use and necessitate different and separately burdensome manual and computer structure, classification, name and bibliographic searches.

Accordingly, Applicant is required under 35 U.S.C. 121 to elect a single disclosed or claimed species of:

a. "Drug" or "electrolyte" AND

b. dipeptide

for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Adams (art unit 1618), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1618)
December 7, 1999

BENNETT CELSA
PRIMARY EXAMINER